



Published in final edited form as:

J Public Health Manag Pract. 2025 ; 31(3): 360–367. doi:10.1097/PHH.0000000000002077.

Validation of a Simplified Laboratory-Based HCV Clearance Definition Using New York City Hepatitis C Program and Surveillance Data

Christina S. Hwang, MPH,

Bureau of Hepatitis, HIV and STI, New York City Department of Health and Mental Hygiene, New York City, New York

Martha P. Montgomery, MD, MHS,

National Center for HIV, Viral Hepatitis, STD, and TB Prevention at US Centers for Disease Control and Prevention, Atlanta, Georgia

Diana I. Diaz Munoz, MPH,

Bureau of Hepatitis, HIV and STI, New York City Department of Health and Mental Hygiene, New York City, New York

Shaoman Yin, PhD, MSPH,

National Center for HIV, Viral Hepatitis, STD, and TB Prevention at US Centers for Disease Control and Prevention, Atlanta, Georgia

Eyasu H. Teshale, MD,

National Center for HIV, Viral Hepatitis, STD, and TB Prevention at US Centers for Disease Control and Prevention, Atlanta, Georgia

Angelica Bocour, MPH

Bureau of Hepatitis, HIV and STI, New York City Department of Health and Mental Hygiene, New York City, New York

Abstract

Context: Laboratory-based hepatitis C virus (HCV) clearance cascades are an important tool for health departments to track progress toward HCV elimination, but a laboratory-based definition of HCV clearance has not yet been validated.

Objective: To compare agreement between a laboratory-based HCV clearance definition with a clinical cure definition.

Design: Observational.

Setting: New York City Department of Health and Mental Hygiene HCV surveillance system data and New York City hepatitis C linkage-to-care program data.

Correspondence: Martha P. Montgomery MD, MHS, National Center for HIV, Viral Hepatitis, STD, and TB Prevention at US Centers for Disease Control and Prevention, 1600 Clifton Rd, MS US12-3, Atlanta, GA 30329 (Lwx6@cdc.gov).

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Participants: Linkage-to-care program participants who were diagnosed with hepatitis C and enrolled in the linkage-to-care program from July 1, 2016, through June 30, 2020.

Main Outcome Measure: Percent agreement between a laboratory-based HCV clearance definition (surveillance system) and a clinical cure definition (program data).

Results: Among 591 program participants with known treatment outcome, the laboratory-based HCV clearance definition and clinical cure definition were concordant in 573 cases (97%).

Conclusions: A laboratory-based HCV clearance definition based on public health surveillance data can be a reliable source for monitoring HCV elimination.

Keywords

continuity of patient care; data systems; hepatitis C; patient navigation; public health surveillance

Introduction

During 2013–2016, an estimated 2.4 million people in the United States had hepatitis C.¹ The United States has established a goal of eliminating hepatitis C as a public health threat by 2030.² To monitor progress toward elimination, public health departments can construct hepatitis C virus (HCV) clearance cascades. HCV clearance cascades display a sequence of steps from testing to cure to reinfection. The goal of a public health cascade is to measure progress along a cascade for an entire population in a jurisdiction. Identification of drop-offs and disparities along the cascade can inform public health interventions. Using a validated and standardized approach to public health HCV clearance cascades is an important step toward achieving the national elimination goal.

Public health departments have designed population-level HCV clearance cascades using various data sources and definitions.^{3–5} The most commonly accessible data source for health departments is laboratory test results reported to the public health surveillance system from health systems and laboratories. Some jurisdictions have mandated HCV test result reporting, including detectable and undetectable HCV RNA results, which can help to monitor current infection status. HCV test results can be deduplicated, merged, and stored in a longitudinal, person-level database. To standardize HCV clearance cascades across jurisdictions, the US Centers for Disease Control and Prevention (CDC) developed laboratory-based HCV clearance cascade guidance for health departments to measure progress toward elimination.⁶ The cascade consists of 5 steps—ever infected, viral testing, initial infection status, cured or cleared, and persistent infection or reinfection. Because most health departments do not have access to treatment data at a population level, the fourth step, HCV cured or cleared, is based on reported laboratory test results. The purpose of this project is to validate the HCV cured or cleared definition in CDC’s HCV clearance cascade using hepatitis C linkage-to-care program data.

Methods

Check Hep C patient navigation program

Check Hep C is a patient navigation program designed to provide linkage to care for New York City (NYC) residents with hepatitis C. To be eligible for the program, patients must reside in NYC, have a positive HCV RNA test, and enroll at one of 14 program sites in NYC. Program sites were located in 4 of 5 NYC boroughs and included federally qualified health centers, nonprofit health systems, and public hospitals.

Once enrolled, patients are supported by patient navigators to complete hepatitis C medical evaluation and treatment. Patient demographic, medical, and treatment information are collected and stored in the NYC Department of Health and Mental Hygiene (DOHMH) Viral Hepatitis Program's Research Electronic Data Capture (REDCap) cloud database.^{7,8} REDCap data are extracted monthly and manually reviewed and deduplicated by Viral Hepatitis Program staff. Patients who were diagnosed with hepatitis C and enrolled in the Check Hep C program from July 1, 2016, through June 30, 2020, were included in this analysis.

NYC hepatitis C surveillance data

The NYC DOHMH hepatitis C surveillance system contains patient demographic and laboratory data records for NYC residents reported to DOHMH through provider and electronic laboratory reporting. Electronic laboratory reporting for hepatitis C is mandated for all positive antibody, positive RNA, and genotype results. Electronic laboratory reporting of negative RNA results was implemented in 2014. Negative HCV RNA results are imported into the surveillance system when they match to a patient who has had a previous positive hepatitis C test result. All hepatitis C tests for the same person are automatically deduplicated. Partial matches that are unable to be automatically deduplicated are manually reviewed by surveillance staff.

Check Hep C patients were matched to the NYC Health Department HCV surveillance registry based on a match key using the first 6 characters from the patient's name and the date of birth. Partial matches were manually reviewed, and matches to more than 1 record in the surveillance registry were resolved.

Clearance definitions and validation analysis

Check Hep C program data and RNA tests reported to the DOHMH were used to define treatment and clearance status. Clinical cure was determined for patients who completed treatment using Check Hep C program data only. Patients were considered to have completed treatment if they had a treatment start date and either (1) had a treatment completion date or (2) the patient navigator otherwise indicated that treatment had been completed. Patients who had a treatment completion date but were either missing status of sustained virologic response (SVR) 12 weeks posttreatment (SVR12) or discontinued treatment were considered to have not achieved SVR12. Clinical cure was abstracted from the Check Hep C data and defined as the navigator indicating that the participant achieved SVR12. Laboratory-based clearance was determined using RNA tests from the DOHMH

hepatitis C surveillance system. Laboratory-based clearance was defined as any negative RNA test result after a positive RNA test after program enrollment.⁶ RNA test results that reported RNA was detected but not quantifiable were considered positive.

Check Hep C program data were used to describe the characteristics of people with HCV infection who were enrolled in the program during the analytic period (July 1, 2016, through June 30, 2020). Characteristics of patients who completed treatment were compared with patients who either did not start or did not complete treatment using a chi-square test. Only patients who completed treatment were included in comparisons of clearance definitions.

For patients who completed treatment, a 2-by-2 table was constructed to summarize how the clinical cure definition compared with the laboratory-based clearance definition. Percent positive agreement (PPA), percent negative agreement (PNA), overall agreement, and Cohen's kappa statistic were calculated to determine the validity of the laboratory-based clearance definition. The kappa statistic is a measure of agreement that ranges from 0 (lowest agreement) to 1 (highest agreement) and takes into consideration that some agreement might occur by chance. Lastly, patients whose clinical cure and laboratory-based clearance determinations were not in agreement were investigated. Reasons for discordance were explored qualitatively using information collected by Check Hep C patient navigators and from RNA testing trends observed in the surveillance data. All statistical analyses were performed using SAS Enterprise Guide 7.1. This project was reviewed by CDC, was exempted from institutional review board oversight because it did not involve human subjects research, and was conducted consistent with applicable federal law and CDC policy (eg, 45 CFR 46.102[l]).

Results

Patient characteristics

We obtained the demographic and clinical information of 1567 participants who enrolled in the Check Hep C Patient Navigation program from July 2016 through June 2020 (Table 1). Of the 1567 participants included in this analysis, 68.5% were male, 30.8% were female, and less than 1% were transgender. The median age at enrollment was 56 years (interquartile range: 47–63 years); 38.0% of participants were older than 60 years and 15.2% were less than 40 years old at the time of enrollment. Nearly three-quarters of the participants were either Black (39.1%) or Latino (34.2%). Almost half of the participants reported ever using drugs (46.5%), and 18.2% reported injecting drugs within the past year. Thirty one percent of participants were ever incarcerated, 5.9% were homeless at any time while enrolled in the program, and 13.0% were living with HIV.

Among 1567 Check Hep C participants, 733 (46.8%) were not started on treatment (Table 1 and Figure). Program notes mention various reasons for not starting treatment including referral to another program, insurance issues, competing health issues, refusal of care, and loss to follow-up. From the NYC surveillance data, 291 of 733 had a subsequent negative RNA after enrollment in Check Hep C, which could be due to either treatment in another program or spontaneous clearance. Participants who either did not start treatment ($n = 733$) or did not complete treatment ($n = 104$) were more likely to report injection or intranasal

drug use in the past year, experience homelessness while enrolled, and were enrolled more often in later program years compared with participants completed who treatment (Table 1).

Comparison of clearance definitions

Of the 834 participants who started treatment, 714 (85.6%) met the inclusion criteria and completed treatment. Of those who completed treatment, 575 (80.5%) participants met the definition for clinical cure, 16 (2.2%) did not achieve clinical cure, and 123 (17.2%) had unknown clinical cure status because data on SVR12 status were missing (Table 2). Upon matching the 575 patients who were clinically cured to surveillance data, 568 met the laboratory-based clearance definition. The laboratory-based clearance definition had a PPA of 98.8% (95% confidence interval [CI], 97.5%–99.4%) and a PNA of 31.3% (95% CI, 14.2%–55.6%) when compared with clinical cure (Table 3). The overall agreement was 97% (95% CI, 95.2%–98.1%) with a calculated kappa statistic of 0.34. There were 18 cases where the laboratory-based clearance and clinical cure determinations were discordant.

Of the 123 participants who completed treatment but for whom clinical cure status could not be ascertained (missing SVR12 status), 112 (91%) were discharged from the program and assumed to be missing treatment outcome due to loss to follow up. Fifty two percent were lost to follow-up prior to their SVR12 appointment. However, among this group, 93.5% (115 of 123) had a follow-up negative RNA test result dated after enrollment in the HCV surveillance system.

Investigation of discordant cases (n = 18)

There were 7 patients who were considered clinically cured but did not meet the laboratory-based clearance definition (ie, did not have negative RNA test results in the HCV surveillance system). Three participants did not have any RNA test results in the HCV surveillance system after their enrollment date (Table 4, scenario 1). One of these 3 participants relocated shortly after participating in the Check Hep C program. RNA testing for SVR12 outside of NYC, if performed, would not have been reported to the NYC DOHMH. Another participant had a single, positive RNA result in the surveillance data 18 months after achieving clinical cure (Table 4, scenario 3). RNA testing patterns showed that the remaining 3 participants tested RNA positive between program enrollment and their treatment completion date; however, these participants did not have any follow-up RNA test results available after treatment completion in the surveillance data (Table 4, scenario 2).

There were 11 participants who did not meet the clinical cure definition but were classified as cleared by the laboratory-based definition (Table 5). Six participants tested RNA negative after treatment completion but had a subsequent positive RNA test result within 6 months of completing treatment (indicative of treatment failure) (Table 5, scenario 1). Three participants tested positive after treatment completion and had subsequent negative RNA tests (Table 5, scenario 2). One participant did not meet the clinical cure definition but had a negative RNA 1 month after completing treatment; clinic notes indicate that the clinic navigator was trying to get this person back into care (Table 5, scenario 3). Lastly, 1 participant discontinued treatment due to adverse effects; their single negative RNA test

result 2 months before completing treatment is indicative of early virologic response rather than cure (Table 5, scenario 4).

Discussion

To achieve the elimination of hepatitis C, it is necessary to evaluate the impact of public health interventions over time and identify areas for improvement. This analysis demonstrated that the laboratory-based clearance definition developed by CDC can be used to accurately monitor HCV clearance rates in NYC. The implications of successfully using negative HCV RNA tests as a proxy for clearance/cure means that the laboratory-based clearance definition can be applied to an HCV clearance cascade while maintaining high PPA.

The high PPA in our study indicates CDC's laboratory-based viral clearance definition can be a useful tool for monitoring HCV elimination efforts in jurisdictions that have access to HCV surveillance data and negative HCV RNA test reporting. The use of HCV surveillance data to predict cure with high sensitivity has been established.^{9,10} These cure algorithms have traditionally relied on multiple RNA tests in definitions of treatment and cure; however, with the simplification of the treatment monitoring guidelines,¹¹ it can be argued that these algorithms can be further simplified as we have demonstrated here. Direct-acting antiviral treatments are highly effective—producing SVR of $\geq 95\%$, even without perfect adherence.^{12–15} Compared with other cure algorithms, the CDC laboratory-based clearance definition is simpler and does not depend on repeated viral load testing, which is no longer recommended during treatment. Given that many people at higher risk for HCV infection (eg, people experiencing homelessness, people with a history of incarceration, and people who use drugs) have competing priorities and needs, one RNA test posttreatment completion is more feasible.¹⁶ In addition to simplifying the cure algorithm, the laboratory-based clearance definition had a high degree of agreement (97.0%) with the clinical determination of individuals who completed treatment and had known SVR12 status.

Conversely, there are limitations to using a single negative RNA test as a proxy for cure. The laboratory-based clearance definition had a lower PNA and incorrectly classified some participants who did not achieve clinical cure as cleared, although this scenario represented $<2\%$ of participants overall. Early negative RNA results prior to treatment completion could indicate that participants were initially adherent to their treatment regimen. Although these participants had an initial undetectable RNA test after starting treatment, they failed to achieve clinical cure (SVR12). The laboratory-based clearance definition was unable to differentiate between negative RNA tests representing SVR and initial treatment response in the absence of clinical cure.

Our study had several limitations. First, this validation study only included participants who were enrolled and completed treatment in the Check Hep C program, and these findings may not be generalizable to other jurisdictions or populations. Additionally, the validation of this laboratory-based clearance definition depends in large part on the strength of the underlying hepatitis C surveillance system and may not be reproducible in health jurisdictions that do not have access to longitudinal surveillance data as well as negative and positive RNA

test results. We were only able to validate the laboratory-based clearance definition among people known to receive treatment as data were not available for those not known to be treated. Therefore, the performance of this clearance definition for people who have not been treated is unknown. The Check Hep C program was designed to improve linkage-to-care and provide one-on-one patient navigation to clinical and other supportive services, which is evidenced to be successful in managing and improving the care of HCV-infected patients.^{17–19} Thus, only a small number did not achieve clinical cure and could be assessed for PNA. The small marginal distribution of patients who completed treatment but were not cured resulted in a low kappa statistic despite high overall agreement, which is a well-described limitation of kappa statistic.²⁰

Lastly, the Check Hep C program was missing data to determine clinical cure status for 17% (123 of 714) of participants who completed treatment; most of whom were lost to follow up. It is plausible that the proportion of participants who achieved clinical cure (SVR12) among this group was different compared to participants for whom clinical cure status was known. However, among participants who had missing clinical cure data, 82% (101 of 123) met the laboratory-based definition of clearance and did not have any positive RNA test after their first negative, suggesting that treatment failure was relatively rare among Check Hep C participants, regardless of whether their cure status was known. This demonstrates that, when utilized in tandem with a robust surveillance system, the laboratory-based clearance definition can be used to infer treatment and cure information at the individual level outside of the clinic setting.

This analysis demonstrates that surveillance data can be used to ascertain clearance or cure using a laboratory-based definition. The usefulness of the definition is contingent upon having access to a robust surveillance system and mandated laboratory reporting of negative RNA test results. Maintaining a longitudinal hepatitis C surveillance database that can capture data for individuals that occur outside of a single clinic or program is critical for understanding testing and treatment trends at a jurisdictional level. Furthermore, health departments need a longitudinal hepatitis C surveillance database capable of recording and deduplicating HCV laboratory tests, including both positive and negative RNA tests. Currently, negative HCV RNA reporting is not mandated in many jurisdictions across the United States⁶; however, federal funding has been allocated to strengthen hepatitis surveillance systems, but mandated reporting of test results is subject to state and local health code laws. The validation and subsequent application of a laboratory-based clearance definition will allow jurisdictions, including NYC, to construct a clearance cascade to identify gaps in clearance/cure and monitor progress toward hepatitis C elimination.

Acknowledgments

Ms. Hwang, Diaz Munoz, and Bocour report funding from New York City Council Discretionary Budget “Viral Hepatitis Prevention” Initiative. For the remaining authors, none were declared.

References

1. Hofmeister MG, Rosenthal EM, Barker LK, et al. Estimating prevalence of hepatitis C virus infection in the United States, 2013–2016. *Hepatology*. 2019;69(3):1020–1031. doi:10.1002/hep.30297. [PubMed: 30398671]
2. U.S. Department of Health and Human Services. Viral Hepatitis National Strategic Plan for the United States: a Roadmap to Elimination (2021–2025). <https://www.hhs.gov/sites/default/files/Viral-Hepatitis-National-Strategic-Plan-2021-2025.pdf>. Accessed June 14, 2024.
3. Moore MS, Bocour A, Laraque F, Winters A. A surveillance-based hepatitis C care cascade, New York City, 2017. *Public Health Rep*. 2018;133(4):497–501. doi:10.1177/0033354918776641. [PubMed: 29902392]
4. Viner K, Kuncio D, Newbern EC, Johnson CC. The continuum of hepatitis C testing and care. *Hepatology*. 2015;61(3):783–789. doi:10.1002/hep.27584. [PubMed: 25348499]
5. Vo QT, Onofrey S, Church D, Cranston K, DeMaria A, Monina Klevens R. The Massachusetts hepatitis C testing cascade, 2014–2016. *Microbiol Insights*. 2019;12:1178636119857961. doi:10.1177/1178636119857961. [PubMed: 31258329]
6. Montgomery MP, Sizemore L, Wingate H, et al. Development of a standardized, laboratory results-based hepatitis C virus clearance cascade for public health jurisdictions. *Public Health Rep*. 2024;139(2):149–153. doi:10.1177/00333549231170044. [PubMed: 37140162]
7. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377–381. doi:10.1016/j.jbi.2008.08.010. [PubMed: 18929686]
8. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: building an international community of software platform partners. *J Biomed Inform*. 2019;95:103208. doi:10.1016/j.jbi.2019.103208. [PubMed: 31078660]
9. Osinubi A, Harris AM, Vellozzi C, Lom J, Miller L, Millman AJ. Evaluation of the performance of algorithms that use serial hepatitis C RNA tests to predict treatment initiation and sustained virological response among patients infected with hepatitis C virus. *Am J Epidemiol*. 2019;188(3):555–561. doi:10.1093/aje/kwy270. [PubMed: 30535062]
10. Moore MS, Bocour A, Jordan L, et al. Development and validation of surveillance-based algorithms to estimate hepatitis C treatment and cure in New York City. *J Public Health Manag Pract*. 2018;24(6):526–532. doi:10.1097/PHH.0000000000000688. [PubMed: 29227418]
11. American Association of the Study of Liver Disease. Monitoring Patients Who Are Starting HCV Treatment, Are on Treatment, or Have Completed Therapy. <https://www.hcvguidelines.org/evaluate/monitoring>. Accessed June 14, 2024.
12. Yek C, de la Flor C, Marshall J, et al. Effectiveness of direct-acting antiviral therapy for hepatitis C in difficult-to-treat patients in a safety-net health system: a retrospective cohort study. *BMC Med*. 2017;15(1):204. doi:10.1186/s12916-017-0969-3. [PubMed: 29151365]
13. Grebely J, Dalgard O, Conway B, et al. Sofosbuvir and velpatasvir for hepatitis C virus infection in people with recent injection drug use (SIMPLIFY): an open-label, single-arm, phase 4, multicentre trial. *Lancet Gastroenterol Hepatol*. 2018;3(3):153–161. doi:10.1016/S2468-1253(17)30404-1. [PubMed: 29310928]
14. Heo M, Pericot-Valverde I, Rennert L, et al. Hepatitis C virus direct-acting antiviral treatment adherence patterns and sustained viral response among people who inject drugs treated in opioid agonist therapy programs. *Clin Infect Dis*. 2021;73(11):2093–2100. doi:10.1093/cid/ciab334. [PubMed: 33876230]
15. Cunningham EB, Hajarizadeh B, Amin J, et al. Adherence to once-daily and twice-daily direct-acting antiviral therapy for hepatitis C infection among people with recent injection drug use or current opioid agonist therapy. *Clin Infect Dis*. 2020;71(7):e115–e124. doi:10.1093/cid/ciz1089. [PubMed: 31677262]
16. Denniston MM, Jiles RB, Drobeniuc J, et al. Chronic hepatitis C virus infection in the United States, National Health and Nutrition Examination Survey 2003 to 2010. *Ann Intern Med*. 2014;160(5):293–300. doi:10.7326/M13-1133. [PubMed: 24737271]

17. Ford MM, Jordan AE, Johnson N, et al. Check Hep C: a community-based approach to hepatitis C diagnosis and linkage to care in high-risk populations. *J Public Health Manag Pract*. 2018;24(1):41–48. doi:10.1097/PHH.0000000000000519. [PubMed: 28141668]
18. Falade-Nwulia O, Mehta SH, Lasola J, et al. Public health clinic-based hepatitis C testing and linkage to care in Baltimore. *J Viral Hepat*. 2016;23(5):366–374. doi:10.1111/jvh.12507. [PubMed: 26840570]
19. Coyle C, Moorman AC, Bartholomew T, et al. The Hepatitis C Virus Care Continuum: linkage to Hepatitis C Virus Care and Treatment Among Patients at an Urban Health Network, Philadelphia, PA. *Hepatology*. 2019;70(2):476–486. doi:10.1002/hep.30501. [PubMed: 30633811]
20. Feinstein AR, Cicchetti DV. High agreement but low Kappa: i. the problems of two paradoxes. *J Clin Epidemiol*. 1990;43(6):543–549. doi:10.1016/0895-4356(90)90158-L. [PubMed: 2348207]

Author Manuscript

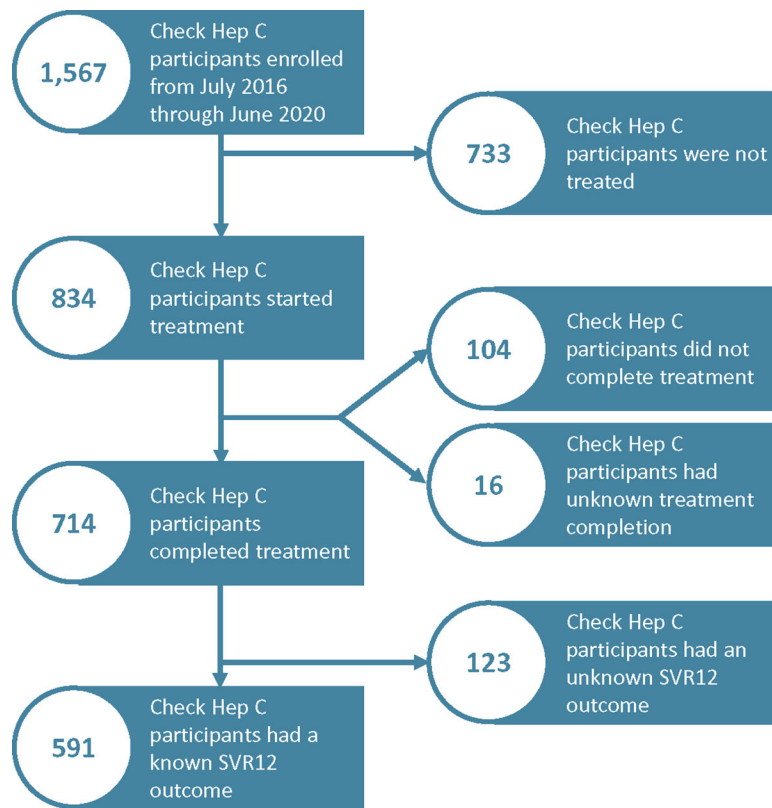
Author Manuscript

Author Manuscript

Author Manuscript

Implications for Policy & Practice

- Developing hepatitis C cascades from public health surveillance data depends on maintaining a longitudinal, patient-level database and receiving comprehensive, electronic laboratory reporting of negative HCV RNA test results.
- In this report, we show that a laboratory-based definition of HCV clearance had high concordance (97%) with a clinical definition of HCV cure in a hepatitis C linkage-to-care program in New York City.
- Negative HCV RNA tests reported to public health jurisdictions can be a reliable proxy for clinical HCV cure and can be a useful tool for monitoring HCV elimination efforts.

**FIGURE.**

Flow Diagram of Check Hep C Patients Included in the Validation Analysis. A Patient Was Considered to Have Started Treatment if They Had A Treatment Start Date. A Patient Was Considered to Have Completed Treatment if They Had A Treatment Start Date and 1) Completion Date or 2) Discharge Notes Indicate that Treatment Was Completed. A Patient Was Considered Having a Known SVR12 Outcome if They Completed Treatment and Have Available Treatment Outcome Data. Abbreviation: SVR12, Sustained Virologic Response at 12 Weeks Posttreatment

TABLE 1
 Characteristics of People Enrolled in the New York City Check Hep C Patient Navigation Program, July 2016-June 2020

	Full Check Hep C Cohort			Completed Treatment			Either Did Not Start or Did Not Complete Treatment ^a			P value
	N	%		N	%		N	%		
Overall	1567	100%		714	45.6%		837	54.0%		
Age at enrollment (years)										
18-39	238	15.2%		121	16.9%		114	13.6%		.06
40-59	734	46.8%		314	44.0%		414	49.5%		
60 +	595	38.0%		279	39.1%		309	36.9%		
Gender										
Male	1073	68.5%		489	68.5%		575	68.7%		.4
Female	482	30.8%		217	30.4%		258	30.8%		
Transgender	12	0.8%		8	1.1%		4	0.5%		
Race and ethnicity										
Asian or Pacific Islander	11	0.7%		7	1.0%		4	0.6%		.3
Black or African American	612	39.1%		324	48.0%		280	41.5%		
Hispanic or Latino	536	34.2%		260	38.5%		272	40.4%		
White	142	9.1%		62	9.2%		79	11.7%		
Other	62	4.0%		22	3.3%		39	5.8%		
Unknown	204	13.0%		39	—		163	—		
Any drug use, ever										
Yes	728	46.5%		417	64.4%		303	67.9%		.22
No	380	24.3%		231	35.6%		143	32.1%		
Unknown	459	29.3%		66	—		391	—		
Injection drug use, ever										
Yes	657	41.9%		376	58.1%		274	62.3%		.17
No	443	28.3%		271	41.9%		166	37.7%		
Missing	467	29.8%		67	—		397	—		
Injection drug use in the past year										
Yes	285	18.2%		150	23.3%		135	31.0%		.005
No	809	51.6%		495	76.7%		301	69.0%		

	Full Check Hep C Cohort			Completed Treatment		Either Did Not Start or Did Not Complete Treatment ^d		P value
	N	%	N	%	N	%		
Declined to answer or unknown	473	30.2%	69	—	401	—		
Intranasal drug use in the past year								
Yes	298	19.0%	159	25.1%	136	31.8%	.02	
No	777	49.6%	474	74.9%	292	68.2%		
Declined to answer or unknown	492	31.4%	81	—	409	—		
Incarcerated, ever								
Yes	491	31.3%	294	49.5%	192	50.5%	.75	
No	498	31.8%	300	50.5%	188	49.5%		
Unknown	578	36.9%	120	—	457	—		
Homeless at any time while enrolled								
Yes	92	5.9%	39	5.8%	50	9.6%	.01	
No	1117	71.3%	636	94.2%	469	90.4%		
Unknown	358	22.8%	39	—	318	—		
Living with HIV								
Yes	203	13.0%	96	13.4%	105	12.5%	.6	
No	1364	87.0%	618	86.6%	732	87.5%		
Program enrollment year ^b								
2016	130	8.3%	73	10.2%	57	6.8%	<.001	
2017	403	25.7%	243	34.0%	152	18.2%		
2018	437	27.9%	220	30.8%	215	25.7%		
2019	427	27.2%	128	17.9%	293	35.0%		
2020	170	10.8%	50	7.0%	120	14.3%		

Abbreviations: HCV, hepatitis C virus; SVR12, sustained virologic response at 12 wk posttreatment.

^aOf those who started HCV treatment, 16 people had unknown treatment completion and were not included.

^bBy fiscal year.

TABLE 2

Comparison of Clinical Cure vs Laboratory-Based Clearance Determinations

Laboratory-Based Clearance (Negative RNA After Positive RNA Test) ^a	Clinical Cure ^b			Total
	Unknown ^c	Yes	No	
Yes	115	568	11	694
No	8	7	5	20
Total	123	575	16	714

Abbreviation: RNA, ribonucleic acid.

^aDefined as any negative RNA test result reported to the health department after a positive RNA test result and after Check Hep C program enrollment.^bDefined by a Check Hep C patient navigator determination that the patient achieved sustained virologic response at 12 weeks posttreatment.^cClinical cure determination was unknown because data on the sustained virologic response at 12 wk posttreatment (SVR12) status was missing.

TABLE 3

Calculated Percent Positive Agreement and Percent Negative Agreement Between Clinical Cure and Laboratory-Based Clearance Determinations^a

	n/N	%	95% Confidence Interval
Percent positive agreement	568/575	98.8	97.5–99.4
Percent negative agreement	5/16	31.3	14.2–55.6
Overall agreement	573/591	97.0	95.2–98.1

^aClinical cure was defined by a Check Hep C patient navigator determination that the patient achieved sustained virologic response at 12 wk posttreatment. Laboratory-based clearance was defined as any negative RNA test result reported to the health department after a positive RNA test result and after Check Hep C program enrollment.

TABLE 4

Summary of Reasons and Interpretations for Participants Identified as Achieving Clinical Cure by the Check Hep C Patient Navigator but Not Cured per the Laboratory-Based Clearance Definition (N = 7)^a

Reason	Interpretation
Scenario 1: No RNA test results in HCV surveillance system after enrollment date (N = 3)	No laboratory evidence of SVR12
Scenario 2: Positive RNA test or genotype results after enrollment and occurred >3 months prior to treatment completion date. No RNA test results after treatment completion date (N = 3)	No laboratory evidence of SVR12
Scenario 3: Positive RNA result 18 months after treatment completion date (N = 1)	No laboratory evidence of SVR12; possible reinfection

Abbreviations: HCV, hepatitis C virus; RNA, ribonucleic acid; SVR12, sustained virologic response at 12 wk posttreatment.

^aClinical cure was defined by a Check Hep C patient navigator determination that the patient achieved sustained virologic response at 12 wk posttreatment. Laboratory-based clearance was defined as any negative RNA test result reported to the health department after a positive RNA test result and after Check Hep C program enrollment.

Summary of Reasons and Interpretations for Participants Identified as Failing to Achieve Clinical Cure by the Check Hep C Patient Navigator but Cured per the Laboratory-Based Clearance Definition (N = 11)^a

TABLE 5

Reason	Interpretation
Scenario 1: First negative RNA test posttreatment followed by a positive RNA test result. • RNA positive result <3 months from first RNA negative test (N = 4) • RNA positive result <3–6 months from treatment completion date (N = 2)	Laboratory evidence confirms treatment failure or reinfection
Scenario 2: Positive RNA test after completing treatment and before first RNA negative test (N = 3)	Laboratory evidence confirms treatment failure; possibly re-treatment
Scenario 3: Negative RNA result(s) after treatment completion date (N = 1)	No laboratory evidence of treatment failure
Scenario 4: No RNA test results after the first RNA negative test or treatment completion date (N = 1)	No laboratory evidence of treatment failure

Abbreviation: RNA, ribonucleic acid.

^aClinical cure was defined by a Check Hep C patient navigator determination that the patient achieved sustained virologic response at 12 wk posttreatment. Laboratory-based clearance was defined as any negative RNA test result reported to the health department after a positive RNA test result and after Check Hep C program enrollment.